

## Food and Drug Administration, HHS

## § 520.100b

treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55659, Nov. 2, 1995]

### § 520.100 Amprolium oral dosage forms.

#### § 520.100a Amprolium drinking water.

(a) *Chemical name.* 1-(4-Amino-2-n-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride.

(b) *Sponsor.* See No. 050604 in § 510.600 (c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Chickens and turkeys*—(i) *Amount.* 20 percent soluble powder.

(ii) *Indications for use.* Treatment of coccidiosis.

(iii) *Limitations.* Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for from 3 to 5 days (in severe outbreaks, give amprolium at the 0.024 percent level); continue with 0.006 percent amprolium-medicated water for an additional 1 to 2 weeks; no other source of drinking water should be available to the birds during this time; as sole source of amprolium.

(2) *Calves*—(i) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations.* Add 16 fluid ounces of the 9.6 percent solution to each 100 gallons of drinking water; or 4 ounces of the soluble powder to each 50 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(ii) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations.* Add 8 fluid ounces of the 9.6 percent solution or 4 ounces of the 20 percent soluble powder to each 100 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63270, Nov. 28, 1997]

#### § 520.100b Amprolium drench.

(a) *Chemical name.* 1-(4-Amino-2-n-propyl - 5 - pyrimidinylmethyl) - 2 - picolinium chloride hydrochloride.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use.* It is used for calves as follows:

(1) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations.* Add 3 fluid ounces of the 9.6 percent solution to 1 pint of water or 3 ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(2) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.